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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,299	08/27/2003	Jeffrey W. Corbett	01320.US1	5386

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EXAMINER
TUCKER, ZACHARY C

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,299	CORBETT ET AL.	
	Examiner	Art Unit	
	Zachary C. Tucker	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12Apr04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 5-15, drawn to formula I compounds, salts or prodrugs thereof, classified in class/subclass 544/405, 406, 407, 408 and 409.

II. Claims 2-4, drawn to a pharmaceutical composition, method of treatment, method of inhibiting binding of CRF to the CRF_1 receptor, classified in class/subclass 514/252.1, 255.05 and 255.06.

The inventions are distinct, each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case diseases treated by the method according to claim 3, such as depression and anxiety, are treatable by many materially different compounds, such as Selective Serotonin Reuptake Inhibitors and GABA agonists. Formula I compounds are also not limited in their utility to only CRF receptor antagonists – WO 00/76980 (Maruyama et al) discloses several compounds according to instant claim 1 which are not characterized as CRF receptor antagonists, rather the compounds in that reference are taught to be protein kinase C inhibitors. Page 48, compounds 26-20, 26-21, 26-22 and 26-23 are compounds according to instant claim 1 wherein V is –NH–; "Ar" is phenyl substituted with methyl or nitro; R_1 is –NH(substituted alkyl) – 2-(N,N-dimethylamino)ethyl; R_2 is $-C(O)NR_4R_5$ - $-C(O)NH_2$; and

"X" is $-CR_3R_5R_5$ – methyl or ethyl. Thus, both conditions (1) and (2) set forth above are met.

According to the MPEP §803, "...a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant." Groups I and II are separately classified.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

This Requirement is further set forth as follows:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, whether Group I or Group II is elected in response to this Requirement.

Due to the breadth of the formula I compounds, election of a single disclosed species is necessary. Formula I compounds encompass a number of different families of patentably distinct chemical compounds for example, variable "V" may be oxygen, sulfur or nitrogen, "Ar" is aryl or heteroaryl rings, "X" is selected from oxygen, nitrogen, alkyl groups, alkanoyl groups and sulfur and "R_1," and "R_2," are widely variable as well, presenting a formidable searching task. There is furthermore much chemical literature published on aryl-substituted pyrazine compounds.

Election of a single disclosed species for searching purposes will greatly simplify the task posed to the examiner by narrowing the scope of what is searched within claim 1, or claims 2, 3 and 4, should applicants elect to prosecute the invention of Group II.

Finally, this Requirement is subject to the following conditions:

The examiner has required restriction between compounds, pharmaceutical compositions, and method of use claims. Where applicant elects claims directed to compounds, and a compound claim is subsequently found allowable, withdrawn pharmaceutical composition claims and method of use claims that depend from or otherwise include all the limitations of the allowable compound claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Pharmaceutical composition claims and method of use claims that depend from or otherwise include all the limitations of the patentable compound** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the compound claims and the rejoined pharmaceutical composition claims and method of use claims will be withdrawn, and the rejoined pharmaceutical composition and method of use claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected compound claim is found allowable, an otherwise proper restriction requirement between compound claims, pharmaceutical composition claims and method of use claims may be maintained. Withdrawn pharmaceutical composition claims and method of use claims that are not commensurate in scope with an allowed compound claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the pharmaceutical composition claims and method of use claims should be amended during prosecution either to maintain dependency on the compound claims or to otherwise include the limitations of the compound claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Specification

The abstract of the disclosure is objected to because it does not

accurately describe the invention. When the invention is a group of chemical compounds, at least some generic structure of those compounds should be set out in the abstract of a patent wherein such an invention is disclosed. Currently, the abstract states that "substituted-1,4-aryl pyrazine derivatives," which is no more descriptive of the compounds than the title of the application is. This description is redundant also because pyrazine is a 1,4 compound by definition. It is suggested that applicants incorporate a generic structure into the abstract, and perhaps rephrase "substituted 1,4-aryl pyrazine derivatives" as "aryl pyrazine derivatives." Applicants may wish to amend the title of the application thusly also. Since the abstract appears on the face of a printed patent, abstracts wherein a generic structure appears provide ease in searching patent literature to those who do so.

Correction is required. See MPEP § 608.01(b).

Conclusion

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Tuesday-Thursday from 8:00am to 4:30pm or Monday from 6:00am to 1:30pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

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